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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,356	12/11/2006	Richard R. Bott	DOG 0101 PA/35319.68	9374

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EXAMINER	
PARK, HAEJIN S	

ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,356	BOTT ET AL.	
	Examiner	Art Unit	
	H. SARAH PARK	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *72 and 74-91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *72, 74-91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/26/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Receipt of Amendment and Remarks dated July 6, 2010 is acknowledged. Claims 72 and 74 - 91 are currently pending. Claim 73 had been previously cancelled.

OBJECTIONS/REJECTIONS WITHDRAWN

2. Prior rejection of claims 72 and 74 – 89 under 35 U.S.C. 103(a) is withdrawn in light of applicants' remarks dated July 6, 2010.

3. All pending claims now stand rejected under new grounds of 35 U.S.C. 103(a) as discussed below.

NEW GROUNDS OF REJECTION- 35 U.S.C. 103(a)

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 72 and 74 – 91 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kosal (US Patent no. 6,545,086 issued on April 8, 2003) in view of Bott et al. (US Pre-Grant Publication no. 2003/0180281 A1 published on September 25, 2003) as evidenced by Woodard et al. (US Patent no. 4,655,767 issued on April 7, 1987).

5. Kosal is directed to oil-in-water (O/W) emulsions comprising a silicone phase with pressure sensitive adhesives (PSAs) in a continuous water phase, and a surfactant (Title; abstract; claim 1).

Concerning claim 72, Kosal teaches that the O/W emulsion is preferably produced by phase inversion and using a surfactant (col.4 ll.24 – 32). The aqueous or

hydrophilic phase of the O/W emultion contains a carrier referred to as a "thickener" including a water soluble polymer such as polyvinyl alcohol (col.5 ll.4 - 13). Kosal further teaches avoidance of hydrocarbon based, i.e. lipophilic, solvents in medical applications such as transdermal drug delivery patches (col.5 ll.26 – 28). Kosal also teaches that the emulsion can be used as release-modifying additives and in medical applications such as transdermal drug delivery patches (col.1 ll.20 – 23; col.5 ll.23 – 24).

Concerning claim 74, Kosal teaches the use of a surfactant in formation of the O/W emulsion while shearing in inversion (col.4 ll.27). By its nature the surfactant forms between hydrophilic and hydrophobic phases to aid formation and stabilization of an emulsion.

Concerning claims 75 – 76, Kosal teaches using polyvinyl alcohol, among others polymers, as a thickener in the aqueous phase of the O/W emulsion as discussed above (col.5 ll.4 – 13). Polyvinyl alcohol is water soluble and in the aqueous phase of the emaulsion.

Concerning claims 81 – 82, Kosal discloses the use of a dispersing agent, i.e. a surfactant, in the inverted mixture and another in the aqueous phase, wherein a more hydrophobic surfactant is added to the oily phase and a less hydrophobic surfactant is added to the aqueous phase (col.4 ll.27 – 35). Kosal also teaches siloxane-based nonionic surfactants (col.4 ll. 11 – 12).

Concerning claims 83 – 84, Kosal teaches emulsion comprising silicone PSAs formed from silicone resins (col.2 ll.31 – 34; col.4 ll.24 – 25).

Concerning claim 85, Kosal teaches that the silicone PSAs generally comprise a product of mixing a silanol-terminated polydiorganosiloxane such as polydimethylsiloxane with a silanol-containing silicone resin, i.e., hydroxy functional silicate resin (col.2 ll.31 – 40, 45 – 49).

Concerning claim 86, Kosal teaches with reference to Woodard et al. that silicone PSAs made by mixing the silanol-terminated polydiorganosiloxane and silanol-containing silicone resin may be chemically treated to react the silanol groups with endblocking agents which introduce triorganosilyl or triorganosiloxy units such as trimethylsiloxy units (col.3 ll. 33 – 37) as taught by Woodard et al. (The '767 patent at col.2 ll.29 – 45). Kosal further explains that the endblocking agent reduces the sensitivity of the adhesive to loss of adhesion in contact with amines (col.3 ll.41 – 43).

6. Kosal does not specifically teach the hydrophilic phase of the O/W comprising a protein active agent as recited in claim 72.

Bott et al. teaches water-in-oil (W/O) emulsions comprising protein active agent in an aqueous phase comprising a carrier such as polyvinyl alcohol, and is directed to sustained release preparations for topical administration of active agents comprising the W/O emulsion wherein the external phase may be silicon PSA taught by Kosal (Title; abstract; paras. [0002], [0008], [0041]). Bott et al. teaches furthermore that silicone surfactants can be added to emulsify the internal phase into very small droplets and enhance the release of the active agent (para. [0008]), as recited in instant claim 82.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Kosal and Bott et al. and prepare O/W emulsion comprising the hydrophobic phase with silicone PSA taught by Kosal for transdermal delivery of protein active agents.

One would have been motivated to do so since Kosal teaches that the silicone PSA provides controlled tack free of hydrocarbon based solvents and enables holding of the active to the skin surface (col.5 ll.14, 17 – 20, 23 – 27), which the skilled person would recognize as advantageous in transdermal drug administration. Kosal further teaches that use of endblocking agents is especially useful for preventing loss of adhesion when the silicone PSA is in contact with amines, comprising proteins (col.3 ll.33 – 43). Moreover Bott et al. discloses that use of emulsion comprising silicone PSA and aqueous phase with protein active agent and a carrier is advantageous for sustained release of the active agent (para. [0001], [0002], [0041]).

7. Concerning claims 77 – 80 and 91 Kosal does not specifically disclose silicone O/W emulsions comprising an enzyme or a biomolecule recited in claim 91 as an active agent.

Bott et al. however teaches inclusion of various natural, synthetic, and engineered enzymes such as oxidoreductases and transferases and antibodies, hormones, and biological modulators (para. [0029]) and various proteases (para. [0049]) as actives in the emulsions.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Kosal and Bott et al. and prepare O/W

emulsion of Kosal for transdermal patches for delivering enzyme active agents taught by Bott et al.

As discussed above, one would have been motivated to do so since Kosal teaches that the silicone PSA provides diverse advantages for use in transdermal medical patches (col.5 ll.14, 17 – 20, 23 – 27). Thus applying the O/W emulsion as taught by Kosal to topical delivery of specific types of enzymes as taught by Bott et al. would have been obvious to a person of ordinary skill in the art.

8. Concerning claims 87 – 88, Kosal and Bott et al. do not explicitly disclose multi-layer dressing comprising a controlled-release layer, an adhesive layer, and an additional layer. However, transdermal drug delivery systems comprising at least three layers were "well known to those skilled in the art" at the time of the invention as evidenced by Woodard et al. (col.3 ll.33 – 50). Woodard et al. specifically teaches transdermal drug delivery device embodiment with amine-resistant silicone adhesives (Title; abstract; Figs. 1 – 2). Specifically the transdermal device shown in Figure 2 of Woodard et al. comprises a drug reservoir layer 20, an adhesive layer 22, and additional layers comprising a backing layer 24 and a polymeric material layers 11 and 12 (Fig. 2). When the drug reservoir layer is adjacent to the substrate, i.e., skin, the polymer layer 11 is disposed adjacent to the adhesive layer 22 and spaced from the drug reservoir layer.

Accordingly, in view of the rejection of claim 72 based on Kosal and Bott et al. above and the state of the art as evidenced by Woodard et al., the multilayer controlled composition in the form of a multi-layer dressing in claims 87 - 88 are not patentable.

9. Concerning claim 89, Kosal does not explicitly teach multi-layer dressings comprising dry controlled-release layer of the O/W emulsion.

Bott et al. however teaches preparation of patch comprising silicone PSA emulsion comprising protein active agent and carrier solution, which is spread onto a Mylar® sheet, dried, and then cut into patches (Examples 7 – 10; paras. [0085], [0089], [0093], [0097]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Kosal and Bott et al. and dry the layer comprising composition of instant claim 72.

One would have been motivated to do so because Bott et al. is drawn to transdermal delivery of proteins via patches. In particular the multi-layer patches of Bott et al. were tested for enzymatic stability or loss of activity, and were shown to provide more stable means of storing and releasing the enzyme (paras. [0088], [0092], [0096], [0100]). Accordingly claim 89 is not patentable in view of the rejection of claim 72 based on Kosal and Bott et al. above.

10. Concerning claim 90, Kosal does not explicitly teach method of delivering the controlled release composition of claim 72 to a substrate.

As discussed above however Kosal and Bott et al. in combination teach delivery of proteins via inverted emulsions comprising silicone with the active in the aqueous phase. Bott et al. further teaches applying the emulsion to a dressing suitable for application directly to skin to protect or administer medicaments to it (para. [0025]).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the O/W emulsion from combination of Kosal and Bott et al. to a dressing, and apply the dressing to a substrate such as skin since transdermal drug delivery by patches was long known in the art as evidenced by Woodard et al. (Figs.1 – 2).

Response to Arguments

11. Applicants' arguments filed July 6, 2010 with respect to claims 72 and 74 – 91 have been considered but are moot in view of the new ground(s) of rejection.

12. Although new grounds of rejection are issued, Applicants' argument relating to Kosal may be pertinent and thus are addressed. Applicants argued that Kosal teaches a pressure sensitive silicone adhesive formulation and that substituting the adhesive of Kosal for the adhesive of Foldvari would still not result in a hydrophobic phase comprising a silicone component (Remarks at 6 - 7, July 6, 2010). This argument would be unpersuasive however as Kosal teaches not only a pressure sensitive adhesive formulation comprising silicone, but also O/W emulsions comprising such silicone PSA as but a component within a continuous aqueous phase of the emulsion (claim 1).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to H. SARAH PARK whose telephone number is 571-270-5258. The examiner can normally be reached on weekdays excluding alternate Fridays, 9 a.m. - 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/HSP/
Examiner, Art Unit 1611

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611